cardica®

Attachment 1 510(k) Summary

FEB 25 2014

510(k) Summary – MicroCutter XCHANGE™ 30 Blue Staple Cartridge

A. Date Prepared

January 15, 2014

B. Applicant Information

Cardica, Inc.
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Redwood City, California 94063
Main: 650-364-9975
Fax: 650-364-3134

C. Contact Person

Vee Arya
Senior QA/RA Manager

(650) 331-7152 direct
(650) 644-7339 mobile
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arya@cardica.com

Alternate Contact:
Frederick Bauer
Vice President of Operations

(650) 331-7163 direct
(650) 331-7195 fax
bauer@cardica.com

D. Establishment Registration Number

3004114958

E. Device Information

Device Class: Class II
Common, Usual or Classification Name: Staple, Implantable
Regulation Number: 21 CFR §878.4750
Product Code: GDW

F. Trade Name

MicroCutter XCHANGE™ 30 Blue Cartridge

G. Legally Marketed Predicate Device(s)

MicroCutter XCHANGE™ 30 (K132581)

H. Device Description

The MicroCutter XCHANGE™ 30 Stapler is a single patient use stapler that delivers two, double staggered rows of 316L stainless steel staples while simultaneously transecting tissue between staple rows. The MicroCutter XCHANGE™ 30 Blue Staple Cartridge is available for deployment with the MicroCutter XCHANGE ™ 30 Stapler which delivers a blue staple (3.5mm) compatible with tissue that can be compressed to 1.5mm. The staple line is approximately 30mm long with a transection length of approximately 27mm.

I. Indications for Use

The MicroCutter XCHANGE™30 is intended for use in multiple open or minimally invasive surgical procedures for the transection, resection, and/or creation of anastomoses in small and large intestine as well as the transection of the appendix.

J. Comparison to Predicate Device

The subject MicroCutter XCHANGE™ 30 Blue Staple Cartridge (polyarylamide) is equivalent in its Indications for Use to the predicate MicroCutter XCHANGE™ 30 Blue staple cartridge (LCP) (K132581). The only modification is a change to the material used for the distal tip of the cartridge insert component from liquid crystal polymer (LCP) to polyarylamide supplied by a vendor. The implantable staple remains unchanged, and there are no other changes to design, operation or materials of the stapler or cartridge except the distal material and colorant of the cartridge insert component within the MicroCutter XCHANGE™ 30 Blue Cartridge.

K. Technological Characteristics

The technological characteristics of the subject MicroCutter XCHANGE™ 30 Blue Staple Cartridge (polyarylamide) are substantially equivalent to the predicate device as demonstrated through verification testing as indicated in Section L "Non-clinical Performance Data" and table below.

The subject MicroCutter XCHANGE™ 30 Blue Staple Cartridge has similar features as compared to the predicate device as shown in table below:

Feature	**PREDICATE DEVICE MicroCutter XCHANGE 30 Blue Staple Cartridge (LCP) (K132581)**	**SUBJECT DEVICE MicroCutter XCHANGE 30 Blue Staple Cartridge (IXEF)**
Deployment Device		
Deployment	Cartridge based deployment (up to 6 deployments per tool) for single patient use	No Change
Shaft Length	340mm	No Change
Transection Line Length	27mm	No Change
End-Effector Opening	2.4mm at tissue stop (proximal); 11.7mm at distal opening	No Change
Shaft Rotation	360°	No Change

Articulation	160° (80° each direction)	No Change
Staple		
Staple Material	Stainless steel (316L)	No Change
Unformed Staple height	3.22mm	No Change
Formed Staple Height	1.4mm (compatible with tissue thickness that can be compressed easily to 1.50mm)	No Change
Formed Staple Configuration	D shaped	No Change
Feature	**PREDICATE DEVICE MicroCutter XCHANGE 30 Blue Staple Cartridge (LCP) (K132581)**	**SUBJECT DEVICE MicroCutter XCHANGE 30 Blue Staple Cartridge (IXEF)**
Staple Line Configuration	Two (2), double-staggered rows	No Change
Staple Line Length	30mm	No Change
Number of Staples Per Deployment	50 (One row of 13 and one row of 12 on either side of transaction line)	No Change
MRI Compatibility	MR-Conditional	No Change
Biocompatibility		
Material Biocompatibility (Delivery Device and Staple)	All components of the Cardica MicroCutter XCHANGE 30 are comprised of materials that were deemed acceptable in accordance with ISO Standard 10993-1.	No Change
Staple Cartridge Cartridge Insert	Liquid Crystal Polymer (LCP) and Stainless Steel	Polyarylamide replacing LCP is the only change. Detailed information on the polyarylamide material was provided via referencing to a Device Master File owned by the manufacturer of this material.
Staple Cartridge Packaging, Sterilization and Shelf Life		
Packaging	Tyvek and Nylon/LDPE/HDPE coextrusion film Pouch	No Change
Sterilization	Gamma radiation	No Change
Sterility Assurance Level	10^{-6}	No Change
Shelf Life	12 months	No Change
Performance		
Tissue Leak Pressure (Bench)	No statistical difference as compared to Covidien ENDO GIA Universal blue staple cartridge ; $p>0.05$	No Change

L. **Non-Clinical Performance Data**

This modification was verified through design verification testing. Bench testing was

conducted and the results demonstrated substantial equivalence to the predicate devices, and that the MicroCutter XCHANGE™ 30 Blue Staple Cartridge (polyarylamide) met design specifications. A summary of the design requirements evaluated were as follows:

- Reliability testing was completed and demonstrated that device performance and strength with the material change meets design specification, post gamma sterilization, transit conditioning, environmental conditioning, and accelerated aging.
- Bioburden testing was conducted and passed in accordance with ANSI/AAMI/ISO 11737-1 Sterilization of Medical Devices- Microbiological Methods Part I: Estimation of Population of Microorganisms on Products.
- Shelf life testing was completed and passed in accordance with ASTM F1980.
- Biocompatibility testing was completed and passed in accordance with ISO 10993-1 requirements.

M. Clinical Performance

The modification was fully verified through design testing described in Section L above, and does not require a clinical study.

N. Conclusions

The subject MicroCutter XCHANGE™ 30 Blue Staple Cartridge (polyarylamide has been carefully compared to a legally marketed device, MicroCutter XCHANGE™ 30 Blue Staple Cartridge (LCP), with respect to intended use and technological characteristics. In addition, non-clinical testing was conducted to verify the performance of the device and ensure the MicroCutter XCHANGE™ 30 Blue Staple Cartridge (polyarylamide) functions as intended and meets design specifications. The comparison and non-clinical results demonstrate that the device is substantially equivalent to the predicate device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

Cardica Incorporated
Ms. Vee Arya
Senior Quality Assurance/Regulatory Affairs Manager
900 Saginaw Drive
Redwood City, California 94063

Re: K140118
Trade/Device Name: MicroCutter XCHANGE™ 30 Blue Cartridge
Regulation Number: 21 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: January 28, 2014
Received: January 29, 2014

Dear Ms. Arya:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140118

Device Name
MicroCutter XCHANGE™ 30 Blue Cartridge

Indications for Use *(Describe)*
The MicroCutter XCHANGE™30 is intended for use in multiple open or minimally invasive surgical procedures for the transection, resection, and/or creation of anastomoses in small and large intestine as well as the transection of the appendix.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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